

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 22

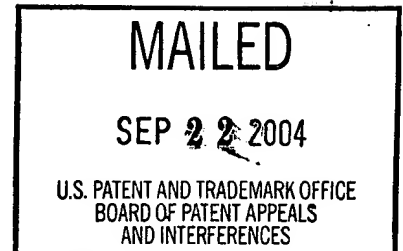
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte KENNETH CORNELL KASPER,
HENRY JEONG, DARIUSH DAVALIAN,
HSHIOU-TING LIU, PAUL L. MILLER, and
DENISE WILLIAMS

Appeal No. 2004-1793
Application No. 09/368,010

ON BRIEF



Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 11, 12, 31-33, 50, 51, and 61, all of the claims remaining. Claim 11 is representative and reads as follows:

11. A monoclonal antibody to tacrolimus produced by a hybridoma produced by fusion of antibody-producing cells from an antibody-producing mammal immunized with tacrolimus derivatized with a carboxymethyl oxime moiety at carbon atom 22 conjugated to a high molecular weight protein with a suitable fusion partner, that has a binding affinity for tacrolimus of about 3.7×10^9 liters/mole, that cross-reacts with 13-demethyl tacrolimus, and that has less than about 8% cross-reactivity to all of the following

tacrolimus metabolites: 15-demethyl tacrolimus; 31-demethyl tacrolimus; 13,31-didemethyl tacrolimus; 15,31-didemethyl tacrolimus; and 12-hydroxy tacrolimus.

The examiner does not rely on any references.

Claims 11, 12, 31-33, 50, 51, and 61 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

We reverse.

Background

Tacrolimus, also known as FK506 or FR-900506, is a known macrolide isolated from Streptomyces tsukubaensis. Specification, page 1. Tacrolimus has immunosuppressive and antimicrobial activity. Id.

"The potency and spectrum of toxicities of tacrolimus requires [sic] sensitive, reproducible, and reliable methods for monitoring the blood concentration of these compounds [sic] after administration to a patient, such [as] a patient undergoing organ transplantation. It is important that such methods be sensitive enough to detect low concentrations of tacrolimus. It is also important that such methods be reliable and reproducible, and avoid interference from compounds such as metabolites of tacrolimus." Page 3.

The specification discloses that "tacrolimus, when derivatized in the non-binding domain, can be coupled to a high molecular weight carrier such as a protein[,] for immunization to produce antibodies." Page 4. In an exemplary embodiment, tacrolimus was derivatized at carbon 22 to produce tacrolimus monooxime (pages 24-26), which was conjugated to keyhole limpet hemocyanin (page 26-27). The tacrolimus-KLH

conjugate was then used to immunize mice and hybridomas were produced using "standard methods." Page 29. The monoclonal antibodies (mAbs) produced by the hybridomas were then screened and a mAb designated 1H6 was selected. The specification discloses that

[t]his antibody has a binding affinity for tacrolimus of about 3.7×10^9 liters/mole, . . . cross-reacts with 13-demethyl tacrolimus, and . . . has less than about 8% cross-reactivity to all of the following tacrolimus metabolites: 15-demethyl tacrolimus; 31-demethyl tacrolimus; 13,31-didemethyl tacrolimus; 15,31-didemethyl tacrolimus; and 12-hydroxy tacrolimus.

Pages 30-31.

Discussion

Claim 11, the only independent claim, is directed to a monoclonal antibody to tacrolimus that is made by immunizing an animal with tacrolimus derivatized with a carboxymethyl oxime moiety at carbon 22 and conjugated to a high molecular weight protein, and that has the same binding properties as mAb 1H6.

The examiner rejected all of the claims as nonenabled. The examiner summarized her position as follows:

[T]he claims, as amended, are based on a specification which does not enable a person skilled in the art to reproducibly obtain even a single monoclonal antibody having the required characteristics as recited in amended claim 11. The claimed monoclonal antibody requires, at a minimum, six very specific binding affinity and cross-reactivity characteristics. Given the state of the art, it would be unreasonable to assume that one skilled in the art could obtain even a single monoclonal antibody meeting the specifications of claim 11 if he prepared and used the immunogenic conjugate described in the working example and screened a very large number of hybridomas.

Examiner's Answer, pages 3-4. See also page 5: "The fact that appellant has provided a description and working example of how he obtained a single monoclonal antibody

having the recited characteristics does not in any way guarantee that another skilled in the art could obtain such an antibody."

"[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[E]nablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

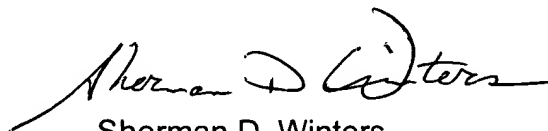
In this case, the examiner has not carried her burden of showing that practicing the claimed invention would be likely to require undue experimentation. We agree with Appellants that the examiner has provided no evidence or sound scientific reasoning to support her conclusion that a person skilled in the art, following the guidance in the specification, would have to experiment unduly in order to generate a monoclonal antibody with the recited characteristics. As Appellants point out (e.g., Appeal Brief, page 7), the specification's working example discloses that, when certain described procedures were followed, a monoclonal antibody having the recited characteristics was produced. The examiner has not convincingly shown, by either evidence or sound scientific reasoning, that a person of skill in the art who carried out the same procedures would be unlikely to obtain a similar result.

It is true that some screening, maybe even a lot of screening, would be required to distinguish between hybridomas that produce mAbs having the recited properties and those that do not. However, the specification discloses the appropriate screening assays and the examiner has provided no evidence that such screening was anything other than routine in the monoclonal antibody art. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . . [T]he key word is 'undue,' not 'experimentation.'" In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The examiner has not met her burden of showing that undue experimentation would have been required to practice the claimed invention

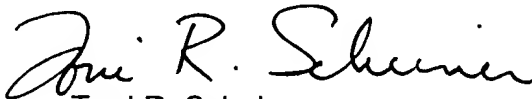
Summary

The examiner has not provided sufficient evidence or sound scientific reasoning to support her conclusion that practicing the claimed invention would have required undue experimentation. The rejection for nonenablement is reversed.

REVERSED



Sherman D. Winters
Administrative Patent Judge



Toni R. Scheiner
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge

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